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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WAX, ROBERT A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/508,828

Applicant(s)

MOSER ET AL.

Examiner

Robert A. Wax

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3,13,14 and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 03162000 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Groups I and II and SEQ ID No. 2 in Paper No. 10152003 is acknowledged. The traversal is on the ground(s) that no lack of unity was held previously, more than one process may appear in an application filed under 35 USC 371, the claims do share a special technical feature, example 17 in the PCT Administrative Instructions is controlling of holding of lack of unity between DNA and protein and that there is a common structure present. This is not found persuasive because the rules for unity of invention are quite clear. Where a set of claims shares a special technical feature that defines over the prior art there is no lack of unity. Since polypeptides that read on claim 1 are taught by the prior art the proteins cannot be said to qualify as a special technical feature and, therefore, a holding of lack of unity is permitted. Applicants are correct in the allegation that multiple processes may not lack unity but such is not the case here where the claims do not share a special technical feature. Applicants are reminded that examiners are not necessarily bound by what occurred in a parent case. The fact that no lack of unity was held in the PCT has no bearing on whether lack of unity is held in the instant case. The fact situation in example 17 of the PCT AI is different from the situation here because the protein does not constitute a special technical feature since it does not define over the prior art. The final argument, that a common structure is present between the polypeptides of SEQ ID

Nos. 1-9 is not correct. That is why they have different sequence identification numbers. No single sequence search would cover them all and, therefore, no common structure is present.

The requirement is still deemed proper and is therefore made FINAL. Claims 3 and 13 are withdrawn from consideration because they do not contain SEQ ID No. 2, the elected sequence. Furthermore, claims 11 and 12 have been characterized by applicants as "method" claims. Examiner disagrees that "means" implies a method when the only claim limitation is a compound, the protein of claim 1. These claims will be treated as composition claims.

#### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 371, which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

3. The information disclosure statement filed March 16, 2000 has been considered. Please see the attached initialed PTO-1449.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 4-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims read on polypeptides that contain at least part of the protein styled as PrP which are recognized by PrP<sup>Sc</sup>-binding substances. Applicants disclose some sequences which they indicate contain part of PrP and which are recognized by PrP<sup>Sc</sup>-binding substances but do not disclose "sequences derived therefrom" (claim 1) or those "coupled with a conformation sequence" that induces "the formation of a defined conformation of the synthetic polypeptide" (claim 4) or "derivative form" (claim 9).

The "sequences derived therefrom" are limitless and include such sequences as Tyr-Tyr-anything at all. Clearly, applicants are not in possession of all such sequences. One basic piece of information is not disclosed and that is what exactly the PrP<sup>Sc</sup>-binding substances are. A single antibody has been disclosed but it is unclear to what portion of the PrP that the antibody binds to and it has not been established that it is specific for the Sc conformation. The area of prion proteins is extremely murky and nobody seems to know exactly what is going on. The absence of proof of the existence of such prion binding substances means that applicants cannot have provided sufficient written description to indicate that they are in possession of the disclosed invention.

The specification contains no disclosure of what sequences may be styled as conformation sequences that induce the formation of a defined conformation of PrP. In fact, since nobody knows what causes the conformational change, there can be no such disclosure and applicants have clearly not provided sufficient written description to indicate that they are in possession of this aspect of the invention either.

***Claim Rejections - 35 USC § 101***

6. Claims 1, 2, 4-12 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants have provided no evidence of the existence of so-called PrP<sup>Sc</sup>-binding substances, without which the assertions of utility are not convincing. Applicants discuss monoclonal antibody 15B3 in paragraph 0026 of the specification but Examiner is not convinced that it actually binds PrP<sup>Sc</sup>. Nobody knows what causes the conformational transformation that results in the disease state and both conformations have the same sequence. The way the antibody was generated did not take conformation into account when it was created from the mapping experiments and thus, it is not clear to which conformer the antibody actually binds. Since the existence of a PrP<sup>Sc</sup>-binding substance is crucial for the invention and since no such substance has been proven to exist the claims lack a specific and substantial utility. Paragraph 0002 of the specification contains the sentence, "It is assumed that PrP<sup>C</sup> proteins are able to

convert normal PrP<sup>c</sup> proteins into the disease-specific folding, thus explaining the infectiousness of PrP<sup>Sc</sup> proteins." This sentence is pure speculation on the part of applicants and cannot be used to support any utility for the claimed invention. The assessment in the prior art is that nobody knows what causes the conformational change and the examiner cannot accept this statement without a significant level of proof.

Claims 1, 2, 4-12 and 15 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 11, 12 and 15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by isolated naturally occurring prion protein.

While claim 1 recites "synthetic" the claim still reads on isolated naturally occurring prion protein. The "means" of claims 11 and 12 and the "kit" of claim 15 do not further limit the protein (the sole ingredient) and thus are anticipated as well.

**Conclusion**

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name and title.

Robert A. Wax  
Primary Examiner  
Art Unit 1653